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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/381,480	12/10/1999	MARK CHEE	018547-03053	4017

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EXAMINER	
FORMAN, BETTY J	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/381,480	CHEE, MARK	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 30 September 2004 in which claims 1, 11 and 15 were amended. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 30 April 2004 under 35 U.S.C. 112, first and second paragraph are withdrawn in view of the amendments. The previous rejections under 35 U.S.C. 102 and 35 U.S.C. 103 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection, necessitated by amendment, are discussed.

Claims 1-15 are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is indefinite for the recitation "the reference sequence" because the recitation lacks proper antecedent basis in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Preliminary Comments

Reiterated from previous action

5. The claims are drawn to a method for analyzing a target nucleic acid comprising the steps of (a) designing an array of probes to comprise probes complementary to a known reference sequence and (e) providing a further array of probes comprising probes complementary to the estimated sequence of the target nucleic acid. The claims are drawn to an array of probes but do not require the probes be immobilized and/or arrayed onto a solid support.

The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111).

6. Claims 13-, 5-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Drmanac (U.S. Patent No. 6,025,136, filed 28 august 1997).

Regarding Claim 1, Drmanac discloses a method of analyzing a target comprising designing an array of probes, not comprising every possible probe of a given length, but comprising a probe set complementary to a known reference sequence (probe set, Column 4, lines 66-67), hybridizing the target to the array wherein the target is a variant of the reference (i.e. allele), determining relative hybridization of the probes to the target and estimating the sequence of the target, designing a further array of probes, based on the estimated sequence, and comprising a probe set comprising probes complementary to the estimated sequence, hybridizing the further array and target, determine relative hybridization and reestimating the sequence (Column 2, lines 44-61 and e.g. Example 4, 6 and 13). As stated above, the instant claims are drawn to an array of probes. The probes are not defined as immobilized or addressed onto a support. Given the broadest reasonable interpretation of the claims, in view of the specification, the claims encompass the probe sets of Drmanac.

Regarding Claim 2, Drmanac discloses the method wherein the steps e-h are repeated until the reestimated sequence is constant between cycles i.e. hypothesis based on hybridization is confirmed (Column 13, lines 5-17).

Regarding Claim 3, Drmanac discloses the method wherein the target is a species variant of the reference (i.e. allele, Column 2, lines 44-61).

Regarding Claims 5-6, Drmanac discloses the method wherein the target shows 80-95% identity with the reference (e.g. single base mutation, Column 3, lines 39-51 and Example 8).

Regarding Claim 7, Drmanac discloses the method wherein the reference sequence is at least 1000 nucleotides long and the probe set and array comprises overlapping probes perfectly complementary to and spanning the reference (Example 16, Column 16, line 41-Column 17, line 62).

Regarding Claim 8, Drmanac discloses the method wherein an estimated sequence includes a nucleotide whose identity is ambiguous and the probe set includes a probe having nucleotides aligned with the position of ambiguity i.e. allele-specific Example 8, Column 9, line 47-Column 10, line 10).

Regarding Claim 9-11, Drmanac discloses the method wherein the reference is at least 1000kb or the human genome (Column 8, lines 55-59).

Regarding Claim 12, Drmanac discloses the method wherein the array comprises a first probe set comprising a plurality of probes of at least 6 nucleotides and complementary to a subsequence of the reference and at least one interrogation position and second, third and fourth probe sets each comprising a corresponding probe for each probe in the first set and identical to at least 6 nucleotides of the sequence from the first probe set except that at least one interrogation position is occupied by a different nucleotide (Example 6, Column 7, line 25-Column 8, line 46).

Regarding Claim 13, Drmanac discloses the method wherein the sequence is estimated by comparing relative binding of four corresponding probes from the four probe sets and assigning a nucleotide as the complement of the interrogation position having the greatest specific binding until each nucleotide has been estimated (Example 6, Column 7, line 25-Column 8, line 46).

Regarding Claim 14, Drmanac the method wherein the target differs from the reference by at least two positions within a probe (Example 6, Column 8, lines 17-20).

Regarding Claim 15, Drmanac discloses a method of analyzing a target nucleic acid comprising designing an array of probe complementary to an estimated sequence of a target wherein the array does not contain every possible probe of a given length, hybridizing the array to the target to determine a re-estimated sequence of the target from the hybridization pattern and repeating the hybridization and determining for each region on the array wherein each

region on the array represents each base of the reference sequence (Example 6, Column 7, line 25-Column 8, line 46).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Drmanac (U.S. Patent No. 6,025,136, filed 28 august 1997) in view of Dietrich et al (U.S. Patent No. 5,861,243, filed 12 October 1990).

Regarding Claim 1, Drmanac discloses a method of analyzing a target comprising designing an array of probes, not comprising every possible probe of a given length, but comprising a probe set complementary to a known reference sequence (probe set, Column 4, lines 66-67), hybridizing the target to the array wherein the target is a variant of the reference (i.e. allele), determining relative hybridization of the probes to the target and estimating the sequence of the target, designing a further array of probes, based on the estimated sequence, and comprising a probe set comprising probes complementary to the estimated sequence, hybridizing the further array and target, determine relative hybridization and reestimating the sequence (Column 2, lines 44-61 and e.g. Example 4, 6 and 13).

Drmanac further teaches their method is an efficient method useful in DNA diagnostics (Column 2, lines 5-12) but does not teach a human reference sequence and primate target sequence.

However, comparison of human reference sequence and primate target sequence was well known in the art at the time the claimed invention was made as taught by Dietrich et al who teach that primates are a desired animal model for the study of HIV genotherapeutics (Column 3, lines 39-50). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the human reference sequence and primate target sequence taught by Dietrich et al to important DNA diagnostics taught by (Column 2, lines 5-12) based on the teaching of Dietrich et al wherein the primate is the desired animal model for the study of HIV genotherapeutics (Column 3, lines 39-50).

9. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Skeina (U.S. Patent No. 5,683,881, filed 20 October 1997) in view of Drmanac (U.S. Patent No. 6,025,136, filed 28 august 1997).

Regarding Claim 15, Skiena discloses a method of analyzing a target nucleic acid comprising designing an array of probes complementary to an estimated sequence of the target wherein the array does not contain every possible probe of a given length (Claim 1, step d), hybridizing the array of probes to the target, determining a re-estimated sequence of the target from the hybridization and repeating the designing, hybridizing and determining (Column 4, lines 5-67 and Claim 2). Skiena is silent regarding the content of the target sequence being sequenced. However, sequencing variants of known sequences was well known in the art at the time the claimed invention was made as taught by Drmanac who teach that sequencing

variants is important for diagnosis and identification of sequence-specific diseases and traits (Column 2, lines 5-12). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the sequencing of Skiena to a sequence variant based on the importance of diagnosing and identifying sequence-specific diseases and traits as taught by Drmanac (Column 2, lines 5-12).

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
December 13, 2004